



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

NOV 14 1996

#21

Francis J. Tinney
Patent Department
Warner-Lambert Company
2800 Plymouth Road
Ann Arbor, Michigan 48105

Re: Patent Term Extension
Application for
U.S. Patent No. 4,376,858

CORRECTED
NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 4,376,858, which claims the human drug product Neutrexin™, is eligible for patent term extension under 35 U.S.C. § 156. U.S. Patent No. 4,376,858 issued March 15, 1983 from an application that claimed priority under 35 U.S.C. § 120 to an application filed on October 31, 1980. Accordingly, the original expiration date of the patent is October 31, 2000. 35 U.S.C. § 154 The period of extension has been determined to be 1,286 days.

In response to a letter dated September 27, 1996 from Stuart Nightingale, M.D., Associate Commissioner for Health Affairs of the Food and Drug Administration, the period of extension has been calculated using the FDA determination of the length of the regulatory review period published in the Federal Register of October 15, 1996. Under 35 U.S.C. § 156(c):

$$\begin{aligned}\text{Period of Extension} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (1,931) + 320 \\ &= 1,286 \text{ days}\end{aligned}$$

Since the regulatory review period began after the patent issue date and there was no determination of a lack of due diligence, the entire period has been considered. The limitations of 35 U.S.C. 156(c)(3) and 156(g)(6) do not operate to reduce the period of extension determined above.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Commissioner will issue a certificate of extension, under seal, for a period of 1,286 days.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	4,376,858
Granted:	March 15, 1983
Original Expiration Date:	October 31, 2000
Applicant:	Norman L. Colbry
Owner of Record:	Warner Lambert Company
Title:	2-4 DIAMINO-5-METHYL-6-[(3,4,5- TRIMETHOXYANILINO) METHYL]QUINAZOLINE SALTS
Classification:	544/291
Product Trade Name:	Neutrexin™
Term Extended:	1,286 days
Extended Expiration Date:	May 9, 2004

Any correspondence with respect to this matter should be addressed as follows:

By mail: Assistant Commissioner for Patents
Box Patent Ext.
Washington, D.C. 20231

By FAX: (703) 308-6916
Attn: Special Program Law Office

By hand: One Crystal Park, Suite 520
2011 Crystal Drive
Arlington, VA

Telephone inquiries related to this determination should be directed to Karin Tyson at (703) 306-3159.



Hiram H. Bernstein
Senior Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

cc: Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 15-22
Rockville, MD 20857

RE: Neutrexin™

FDA Docket No.: 94E-0099